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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,451	09/19/2003	Anthony D. Prescott	EAG-023	8367
36822	7590	06/29/2004	EXAMINER	
GORDON & JACOBSON, P.C. 65 WOODS END ROAD STAMFORD, CT 06905			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,451

Applicant(s)

PRESCOTT ET AL.

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/19/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19,22,23,24,25 and 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Prescott (5554188).

Prescott discloses an implant that appears to be within the range as claimed by applicant. (Comparing the dimensional relationship as shown in the figures)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea et al (4292693).

Shea discloses a stapedial prosthesis sized to be implanted as a replacement for the stapes between the incus and the oval window of the middle ear, comprising: a body defining a bucket sized to at least partially receive a portion of the incus, and a shaft

Art Unit: 3738

having a length sufficient to extend from the incus to the oval window; and b) a handle coupled to said bucket. Stainless steel is well known for spring it spring-like properties and it's use as a spring in the otic art is well documented (see eg. Lenkanskas).

Claim 27 see stapedial prosthesis of Shea et al.

Claim 28, the language of the claim does not preclude the intermediate product where the first and second ends are not coupled.

Claim 29, the method for attaching the stapedial prosthesis of Shea, et al would inherently meet the steps as outlined by applicant.

Claims 2-7,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea et al (4292693) as applied to claim 1 above, and further in view of Kurz et al (5514177).

Kurz et al teaches that the bight for capturing the incus is formed of pure titanium. While Shea et al, an older patent, utilizes stainless steel, the art shows the benefits in using titanium as a spring-like element for capturing the incus. To replace the stainless steel of Shea et al with titanium for better spring-like and biocompatible properties would have been obvious from the teaching of Kurz, et al.

Claim 4, as worded does not appear to distinguish over the conformation of the bucket and U-shaped handle of Shea, et al. Certainly, the handle has two ends and once inserted into the bucket, the handle is subjected to load.

Claim 5, the holes of Shea et al are configured diametrically opposite on the bucket.

Claims 6 and 7, see notch 26 in the rim which terminates above the holes of the bucket of Shea et al.

Claim 9, as broadly worded the handle of Shea, et al is rotatably coupled to the bucket.

Claim 10, see pure titanium of Kurz, et al.

Claim 13, the structure of Shea et al as modified would inherently yield a spring loaded handle as broadly claimed.

Claims 8,11,12,14 and 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea et al (4292693) as applied to claim 1 above, and further in view of Muller (6540661).

Muller teaches a bucket type capturing mechanism comprising slots formed therein. While the bucket of Muller is not intended for capturing the incus, the principle of providing slots in a wall member to increase wall flexibility is well known in any art. To provide slots in the bucket of Shea et al to increase the wall flexibility so as to offer the surgeon a more effective capturing of the incus would have been obvious to one with ordinary skill in the art from the teachings of Muller.

Claims 11 and 12, see body composition of the slotted bucket of Muller.

Claims 15-17, while Muller is silent as to the dimension of the slot, it appears that in comparing the two devices, applicant's and Muller, the slot would approximately fall within the range as claimed.

Claim 18, the bottom of the bucket of Shea et al is closed.

Claims 30-39, the method for attaching the stapedial prosthesis of Shea, et al as modified by Muller would inherently meet the steps as outlined by applicant.

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shea et al and further in view of Gersdorff (4740209).

Gersdorff teaches the combination of a bucket and an enlarged foot plate used in stapedial reconstruction. To add footplate to the bucket/shaft element of Shea et al to improve acoustic transmission would have been obvious from the teachings of Gersdorff.


Claim 22, to make the footplate of plastipore similar to the main body of Shea et al would result in a porous foot plate to aid in tissue ingrowth to stabilize the implant.

Claims 23 and 24, element 8 of Gersdorff appears to be within the range as claimed by applicant. (Comparing the dimensional relationship as shown in the figures)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
JUNE 15, 2004